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EXAMINER

TRAN, SUSAN T

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claim Rejections - 35 USC § 103

Claims 1-5, 7 and 9-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Begleiter EP 0 217 821 B1 (Begleiter I), in view of Begleiter II (Edible Holography).

Begleiter I teaches an edible holographic element comprising a polymer such as hydroxypropyl methylcellulose (column 2, lines 13-30). The edible holographic further comprises plasticizer such as polyhydric alcohol and dextrose (column 2, lines 49 through column 3, lines 1-33).

Begleiter I does not teach the pharmaceutical dosage form comprising active substance. However, Begleiter II teaches a holographic composition for compressed candies, children's vitamins, and form of brand identification (page 104). Begleiter II further teaches a holographic composition comprising cellulose such as HPMC (page 103). Thus, it would have been obvious to one of ordinary skill in the art to modify the teachings of Begleiter I in view of the teachings of Begleiter II to obtain the claimed invention, because Begleiter I teaches an edible holographic composition suitable for candies and other food products, and because Begleiter II teaches holographic can be applied to food products such as candies, children's vitamins, and other form of brand ID.

Response to Arguments

Applicant's arguments filed 04/17/08 have been fully considered but they are not persuasive.

Applicant argues that the cited references direct one to use cold pressing powders to create pharmaceuticals having the ability to produce holographic images and effects. The prior art mentions HPMC and other complex polysaccharides, but only to form dehydrated films for use on confections and like foodstuffs. The prior art teaches plasticizers, but not in the presently claimed combination for the presently claimed purpose. The Examiner also cites Begleiter I and Begleiter II as teaching the use of HPMC. However, as described in Begleiter I, and as stated at the cited page 103 of Begleiter II, "complex polysaccharides [including modified celluloses] which have been used as those which can be dehydrated from a liquid solution." The cited prior art therefore teaches away from the use of HPMC as a thermoformable layer that receives a diffraction relief. The Examiner on page 4 states "cellulose such as HPMC is thermoformable." Applicant is not aware of such a teaching in the prior art of record.

However, in response to applicant's argument that the cited prior arts do not teach *HPMC that is thermoformable and stable to receive and maintain the diffraction relief*, absent of evident to the contrary, the burden is shifted to applicant to show that the HPMC of the cited prior arts is not capable of thermoform, and is not capable of maintaining the diffraction relief. Applicant's attention is called to claim 17 in Begleiter I for the teaching of contacting an edible composition with a relief mold, allowing the position to harden and removing the molded product from the mold, characterized in

that an edible organic polymer is contacted with a high resolution diffraction relief mold and a holographic image is conferred on said product.

Further, in response to applicant's argument that the cited references direct one to use cold pressing powders to create pharmaceuticals having the ability to produce holographic images and effects, it is noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Begleiter II is cited solely for the teaching of including vitamins in candies and/or other edible products with holographic design is well known in the art.

Applicant states that the Examiner also argues obviousness on page 4 bottom, page 5 top. Begleiter II is cited as teaching "kid vitamin candy," argued as "pharmaceutical dosage forms." But this cited reference in Begleiter II is in the part of Begleiter II teaching that for pharmaceuticals, one does not use Begleiter I teachings, instead one compresses a powder. As stated in the Rule 132 Declaration, para. 9, pressing a powder by itself in a tablet press to pick up a hologram that is a part of the punch had a number of serious commercial problems such as the punch/diffraction grating wearing out very quickly ("wore out within a few cycles") or becoming clogged after a few tries; also the tablet did not have good brightness or stability (in contrast to the description of stable in the present specification). The claimed invention defines a

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product using a material that can be applied to a tablet. The layered tablet can then be handled, and that rapidly flows and sets at just the correct time, all while picking up the fine grating structure (but importantly not clogging or destroying the transfer plate, releasing from the impression plate for the next cycle to begin), and then holding a hologram with high diffraction efficiency (bright) in a stable or controllable way.

However, in response to applicant's argument with respect to the process/method for applying the holographic product onto the candy, it is noted that the present claims are directed to a product claims, not method claims. Nowhere in the claims require any method steps. Further, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a product using a material that can be applied to a tablet. The layered tablet can then be handled, and that rapidly flows and sets at just the correct time, all while picking up the fine grating structure (but importantly not clogging or destroying the transfer plate, releasing from the impression plate for the next cycle to begin), and then holding a hologram with high diffraction efficiency (bright) in a stable or controllable way) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that whether or not any material could be thermoformed to produce a diffraction relief in a layer of a pharmaceutical dosage form was not obvious to the Begleiter of Begleiter I and Begleiter II. Moreover, the Declaration provides facts

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from the person most knowledgeable about the products produced under the teachings of Begleiter I and Begleiter II as to the performance of those products and their suitability as pharmaceutical dosage forms. The prior art images faded rapidly. Begleiter II directly states that the holographic images and effects created by its teachings did not last beyond 9 months. The Declaration provides specifics, "data." It notes "conditions" such as prior art images produced in cold compressed tablets as disappearing when breathed upon (para. 11). In the same paragraph, it describes prior art heat stamping of relief on hard candy materials as producing images that "lasted only a few weeks, even under perfect conditions." (emphasis supplied) "Stable" as used in the claims is defined in the specification. Pharmaceutical markings clearly must be stable -- last much longer than the stated durability of the Begleiter I and Begleiter II images and effects.

However, in response to applicant's argument with respect to the showing that Begleiter II product did not last beyond 9 months, it is noted that Begleiter II is not cited from the teaching of cold pressed powder holographic element. Begleiter is cited solely for the teaching of including vitamins into candy is useful to administer vitamins to children. Further, the food product taught by Begleiter I does not explicitly exclude any vitamins and/or minerals that could possibly be active agents. Moreover, the present claims recited a product claims, there are no requirements of any process steps.

Applicant states that to recap certain of these dependent claims, they include: claims 3, 5, 19-24 relating to a pharmaceutical dosage form that responds controllably to temperature and/or humidity to provide a visual indication of the environmental

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history and efficacy of the dosage form; claims 15 and 16 relating to a heat fusion bond between the outer layer and a core; claim 17 relating to the outer layer constituting a capsule; the "strip" dosage form of claim 18; the use of waxes in a layer forming a diffraction relief to control the response of the relief to temperature (claims 11, 12/11, 13/12, 16, 20, and 21); as well as claims 25-28 relating to features of a pharmaceutical dosage form of the present invention that also resists twinning.

However, in response to applicant's arguments with respect to the properties of the claimed product, absent of evident to the contrary, the burden is shifted to applicant to show that the cited prior art's product does not exhibit at least similar properties. Begleiter teaches the use of the same materials that is capable of receiving the holographic image, thereafter the holographic product is conferred to confection, candy and other products (columns 1-2 and 4).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606.

The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1618